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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,669	12/12/2005	Kexin Xu	7605 P 002	4371

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McDERMOTT WILL & EMERY LLP
227 West Monroe Street
Chicago, IL 60606-5096

EXAMINER

WINAKUR, ERIC FRANK

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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04/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,669	Applicant(s) XU ET AL.	
	Examiner Eric F. Winakur	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2009 and 15 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/15/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed specification (page 6, line 13) explicitly indicates the range is 0.8 - 2.5 μm , and thus does not support the amended range of "about" 0.8 - 2.5 μm , which does not precisely correspond to the scope of the disclosed range.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 - 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 1, it appears that a step of "providing" the elements (incident unit, receiving unit, data processing unit) should be set forth, to permit details of the structure of these elements to be positively set forth in the claim (or in the dependent claims) with a corresponding limiting effect on the claimed method; the recitation of lines 13 - 15 regarding adding the overlapped and

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adding the non-overlapped spectra is unclear - in particular, it is unclear how the adding is meant to be implemented. With regard to claim 4, it is unclear what further limitation is set forth, as all possible arrangements appear to be set forth, which are necessarily inherently covered by the base claim. With regard to claims 5 - 8, the positively claimed steps are not clearly recited. With regard to claim 9, the term "LDs" should be defined at its first recitation in the claim as meaning "laser diodes"; the final five lines do not clearly set forth a structure. With regard to claim 11, it is unclear what further limitation is set forth, as the claim appears to essentially repeat what is recited in the base claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 4, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Scecina (WO 01/16577). Scecina teaches a measurement method and apparatus that enhances a spectral measurement by adding a limited number of discrete wavelengths in the measured full spectrum to gain an improvement in analyte measurement accuracy (page 3, line 27 - page 5, line 18). A variety of constituents, including glucose, can be measured by the arrangement (page 10, lines 17 - 19). Further details are provided on page 10, line 28 - page 11, line 20; page 12, lines 1 - 27; and page 15, lines 23 - 32.

Claim Rejections - 35 USC § 103

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scecina as applied to claim 1 above, and further in view of Caro. Scecina discloses that both spectral and discrete optical measurements are performed, to yield improved measurement accuracy, as detailed above, and that measurements can be performed simultaneously or sequentially (page 11, lines 17 - 20), but do not particularly teach that an acoustic optical filter is used for selectively splitting light from the broadband source. Caro teach an optical measurement arrangement and method that can use a variety of optical elements, including an acoustooptic tuneable filter, for selectively splitting light from a broadband source for performing optical measurements (column 14, line 49 - column 15, line 36). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Scecina to include an acoustic optical filter, as taught by Caro, since Scecina requires an optical element for selectively splitting light from the broadband source, and Caro teaches that an acoustic optical filter is a suitable element to perform such a function in an optical measurement arrangement.

9. Claims 5 - 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sceina as applied to claim 1 above, and further in view of Caro, Dähne, and Swedlow. Scecina discloses that both spectral and discrete optical measurements are performed, to yield improved measurement accuracy, as detailed above, and that measurements

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can be performed simultaneously or sequentially (page 11, lines 17 - 20), but do not particularly teach that an acoustic optical filter is used for selectively splitting light from the broadband source. Caro teach an optical measurement arrangement and method that can use a variety of optical elements, including an acoustooptic tuneable filter, for selectively splitting light from a broadband source for performing optical measurements (column 14, line 49 - column 15, line 36). As Scecina teaches that the measurements can be performed sequentially, it would have been within the skill of the art to particularly determine the relation between the measurements from the continuous light source and the discrete light sources. Further, Caro teaches that the measured analog signal may be amplified, filtered, or otherwise processed to be made compatible with analog-to-digital converters in the arrangement (column 11, lines 16 - 24). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Scecina to include an acoustic optical filter, as taught by Caro, since Scecina requires an optical element for selectively splitting light from the broadband source, and Caro teaches that an acoustic optical filter is a suitable element to perform such a function in an optical measurement arrangement. Further, as Caro details, one of skill in the art would have knowledge of the well known electronic components of the arrangement. In addition, the person of skill in the art would also have knowledge of the normal range of expected values of the physiological signals that they were interested in measuring and some appreciation of the optical properties of the measured tissues, and thus would be able to predict expected signal levels that would reach the detection and amplification components of the sensing arrangement for different conditions. Also, one of skill would

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attempt to avoid having either an under- or over saturation situation of any of the electronic components arise while operating the device, since the processed value would not be physiologically accurate. Thus, a pertinent question to contemplate would be how this could be achieved, and one would recognize that a known manner to provide this is by controlling the signal level at the input of the ADC to be near the center of the operating range of the ADC (as given in Swedlow et al., column 4, lines 20 - 31) and Dähne et al. teach that a spectrophotometric arrangement can include a gain programmable amplifier. It is noted that Caro mentions that the measured signal can be amplified and processed prior to digitization in order that they be made compatible with the analog to digital converters (column 11, lines 16 - 21; column 16, lines 18 - 25), but do not provide particular details of how this would be implemented. From this knowledge, one of skill could design and optimize system performance to best account for strengths and weaknesses of the different components in relation to the measurements of interest. In this case, one would at a minimum want to relatively increase the gain for weaker signals and relatively decrease the gain for stronger signals to keep the input near the center of the operating range of the ADC and avoid over or under saturation situations at the ADC. Further, a review of the glucose absorption curve (Dähne et al., Figure 5) indicates to one of ordinary skill in the art where these conditions would occur (gain would need to be inversely related to absorption, and thus lower at the lower wavelengths of interest and higher at the higher wavelengths of interest). As such, one would desire to vary the gain in coordination with the scan, regardless of the particular scan protocol implemented, as Caro, Dähne

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et al., and Swedlow et al. all teach the importance of maintaining the amplified signal in the range of the ADC and one would recognize that the gain of the amplifier would necessarily be varied in inverse relation to the absorption of the measured analyte to provide such a result.

10. Claims 9, 10, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Secina in view of Caro, for the reasons given in paragraphs 4 and 6 above.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Secina and Caro as applied to claim 9 above, and further in view of Dähne and Swedlow, for the reasons given in paragraph 7 above.

12. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Secina and Caro as applied to claim 9 above, and further in view of Rebec et al. The combination teaches all of the features of the claimed invention including the use of optical fibers, but does not particularly teach that the light is directed to the tissue and collected via an arrangement of optical fibers having a ring arrangement. Rebec et al. teach an analyte detection system that includes delivery and receive optical fibers (Figures 1, 5a, 5b) having concentric ring shaped distributions of the fibers. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Secina and Caro to utilize a ring shape arrangement of the optical fibers, as taught by Rebec et al., since the combination discloses use of optical fibers and Rebec et al. teach a suitable arrangement to implement the fibers.

Response to Arguments

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13. Applicant's arguments, see remarks, filed 12/18/09, with respect to the rejection(s) of claim(s) 1 - 15 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly applied art, as given above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571/272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768